AUG 15 2003

Exhibit #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: k031958.

1. **Submitter's Identification:**

   Microlife Intellectual Property GmbH, Switzerland
   Max Schmidheiny-Strasse 201
   9435 Heerbrugg / Switzerland

   Date Summary Prepared: June 24, 2003

2. **Name of the Device:**

   Microlife Instant Digital Electronic Thermometer, Model QT1JA1

3. **Predicate Device Information:**

   AVITA Instant Thermometer, Model IT101, K#012136, AVITA International Corporation

4. **Device Description:**

   This predictive (instant) digital electronic thermometer enables very fast and reliable measurements. With its predicative technology, this thermometer offers very high clinical accuracy and, has been designed to provide maximum user-friendliness.

   The basic principle of this thermometer is that a change of thermistor resistance, caused by changes of temperature, are converted to changes of frequency of R-C oscillator circuit. Therefore, temperature can be given by measuring the frequency of the oscillator.

   For a given time period by applying to R-C oscillator circuit, changes of temperature will correspond to changes of pulse number.

5. Intended Use:

The Microlife Instant Digital Thermometer, Model, QT1JA1 is used for the intermittent measurement and monitoring of human body temperature, orally, rectally and under the arm.

The Microlife Instant Digital Thermometer, Model, QT1JA1 is a hand-held, non-sterile, reusable clinical thermometer intended for the determination of human temperature in either predictive (Instant) mode (5- seconds orally, 7- seconds rectally and under the arm—predictive temperature), or standard mode (actual determination of temperature).

The device is for the adult and pediatric population.

6. Comparison to Predicate Devices:

The Microlife Instant Digital Electronic Thermometer, Model QT1JA1 is similar in design and intended use to the AVITA Instant Thermometer, Model IT101, K#012136, AVITA International Corporation, differing mostly in response time, physical dimensions, a wider measurement range, display resolution and wider operating conditions.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1112, as well as IEC60601-1 and IEC60601-1-2 requirements.

Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers.

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted using the Microlife Instant Digital Electronic Thermometer, Model QT1JA1. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Microlife Clinical Test Protocol outline.

9. Conclusions:

The Microlife Instant Digital Electronic Thermometer, Model QT1JA1 has the same intended use and similar technological characteristics as the AVITA Instant Thermometer, Model IT101. Moreover, bench testing contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Instant

Digital Electronic Thermometer, Model QT1JA1 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2003

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K031958
Trade/Device Name: Microlife Instant Digital Thermometer, Model, QT1JA1
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: June 24, 2003
Received: June 25, 2003

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K031958

Device Name: Microlife Instant Digital Thermometer, Model, QT1JA1

Indications For Use:

The Microlife Instant Digital Thermometer, Model, QT1JA1 is used for the intermittent measurement and monitoring of human body temperature, orally, rectally and under the arm.

The Microlife Instant Digital Thermometer, Model, QT1JA1 is a hand-held, non-sterile, reusable clinical thermometer intended for the determination of human temperature in either predictive (Instant) mode (5- seconds orally, 7-seconds rectally and under the arm—predictive temperature), or standard mode (actual determination of temperature).

The device is for the adult and pediatric population.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The Counter Use** ✓
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Patricia Cusenza

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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